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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/636,052

08/07/2003

Norman Krause

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7590

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/636,052	<b>Applicant(s)</b> KRAUSE ET AL.	
	<b>Examiner</b> Michael Borin	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/21/2005, 08/07/2003</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of Claims**

1. Claims 1-20 are pending.

Response to election of species requirement filed 02/25/2008 is acknowledged. Applicant elected, species of claims 4 and 14 for groups A and B, respectively. Claims 3 and 17-20 are withdrawn from further consideration under 37 C.F.R. 1.142(b) as not readable on the elected species, there being no allowable generic claim.

Claims 1,2, 4-16 are under examination.

### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statements filed 10/21/2005 and 08/07/2003 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered. Note that the references which do not have year of publication are crossed out on IDS.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear, how, in the case when only one image is being used the “images are orthogonal to each other”.

***Claim Rejections - 35 USC § 102 and 103.***

4. Claims 1,2,4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (US 6,112,109; reference in IDS) in view of DiGioia et al (Computer Assisted Orthopaedic Surgery. Image Guided and Robotic Assistive Technologies. Clinical Orthopaedics, 1995, 354, p. 31-39; reference in IDS) and Background art (specification, p. 4).

The instant claims are drawn to method of generating an updated surgical plan, the method comprising:

- generating a three dimensional (3D) model of a bone, based on the 3D model,
- generating a surgical plan including:
  - one or more locations on the bone upon which to dispose one or more fixators,and
  - one or more settings of one or more struts of the one or more fixators, and
- based on data associated with the placement of the one or more fixators disposed on the bone, generating an updated surgical plan including updated settings for one or more of the one or more struts

Claim 2 specifies that generating a 3D model is based on

- one or more two dimensional (2D) images of the bone and
- one or more 3D bone templates

Claim 4 specifies that locations on the bone are locations for pins for fixators. Further, claims 7-10 specify that the data of locations are based on one or more images of fixators (claim 8), such as X-ray images (claim 10), which can be orthogonal to each other (claim 9)

Claim 5 specifies that settings of struts include one or more periodic adjustments of the struts

D'Urso discloses a method of constructing/modeling of a three-dimensional image of anatomical features such as bone by determining one or more contours of the bone based on one or more two-dimensional images or 2D projections of the bone. The contour of the bone is based on modifying 3D template model of the bone to generate a 3D model of the bone (col. 5, lines 11-33).

D'Urso discloses that the 2D image data is digitized X-ray images (col. 5, lines 34-36).

D'Urso further discloses that the method described above include deforming based on the 3D template model, determining the 2D fiducial geometry of the bone, and fiducial geometry, deforming the 3D template model to generate a 3D model having 2D projections that are similar to the 2D images. In addition, the deforming based on the 3D template model includes generating a 3D lattice, and deforming the 3D lattice to generate 2D projections that are similar to the 2D images. Furthermore, the method

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includes deforming the 3D lattice computing one or more free form deformation parameters for the 3D lattice, and iteratively determining values of the FFD parameters for generating 2D projections that are similar to the 2D images (col. 7, line 57 - col. 8, line 38)

The reference does not teach using the described 3D model of a bone to generate a particular surgical plan for bone distraction that includes such considerations as locations on the bone where to dispose fixators, or settings of struts of fixators.

DiGioia et al teach that planning of orthopedic surgery benefits from use of computer assisted planning tools comprising imaging capabilities. (See also references discussed in Background Section of the instant application, pages 7,8). Thus, the reference teaches:

...Once the optimal plan is developed, surgeons will be able to implement that plan accurately and precisely. Only by coupling preoperative medical images and optimized plans with accurate tools used during surgery will the full potential of these new technologies be realized.

Image guided surgical navigational tools also will provide clinical researchers with a new generation of measurement devices and intraoperative sensors which will permit the quantification of current clinical practice and provide information about surgical procedures and techniques never before available during surgery. Such quantification of intra- operative variables then can be used to analyze and validate more precisely long term clinical outcomes

As disclosed in the Background section of the instant specification, with respect to bone distraction process,

At present, the following nominal steps are performed during the bone distraction process: (1) Determine an appropriate frame size for the fixator (e.g., for the Ilizarov fixator 20); (2) Measure (e.g., from X-rays) the deformity of bone fragments (or the anticipated fragments after surgically cutting the bone) and obtain six parameters that localize one fragment relative to the other; (3) Determine (or anticipate) how the fixator frame should be mounted on the limb; (4) Input the parameters and measurements to a computer program that generates the strut lengths as a function of time required to correct the deformity; (5) Mount the fixator frame onto the bone fragments; and (6) Adjust the strut lengths on a daily basis according to the schedule generated in step (4).

The steps outlined in the preceding paragraph are currently executed with minimal computerized assistance. Typically, surgeons manually gather or determine the required data (e.g., fixator frame size,

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bone dimensions, fixator frame mounting location and orientation, etc.) and make their decisions based on hand-drawn two-dimensional sketches or using digitized drawings obtained by tracing X-ray images.

In *KSR Int'l v. Teleflex*, the Supreme Court, in rejecting the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, indicated that

The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.

*KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007).

Applying the KSR standard of obviousness to D'Urso, DiGioia and art disclosed in the Background section, Examiner concludes that the combination of the references is an obvious use of known technique to improve similar methods.

The nature of the problem to be solved, effective preparation of surgical plan for bone distraction surgery, may lead inventors to look at references relating to possible improvements, such as use of computer assisted planning tools comprising imaging capabilities comprising three-dimensional, rather than two dimensional, model of a bone. Therefore, it would have been obvious to gather or determine the required information such as fixator frame mounting location and orientation, frame size, bone dimensions, etc., and make their decisions based on computational method of generating 3D model of a bone. Using the known technique of generating 3D model of

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a bone to provide necessary information for preoperative planning of bone distraction surgery would have been obvious to one of ordinary skill.

With respect to dependent claims 4-6,11-13 , if there are any differences between Applicant's claimed method and that of the prior art, the differences would be appear minor in nature. Although the prior art do not teach the various details of plan development and evolution, , it would be conventional and within the skill of the art to select and/or determine all necessary conditions for the intended purpose of quality planning of successful bone distraction procedure and selection of appropriate conditions for fixator frame mounting location and orientation, frame size, bone dimensions, etc., as well as generation of surgical procedure using simulated computer animation, are conventional and within the skill in the art to which this invention pertains.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double



patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1,2,4-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12, and claims of U.S. Patent No. 6,701,174. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the referenced claim(s) because the examined claim is either anticipated, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir.1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir.1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 of the '174 patent is directed to creating a surgical plan based on 3D model, the latter created by extracting a bone contour from a plurality of 2D X-ray images, identifying the bone contour on a 3D template bone model, adjusting size and position of the template bone model based on the bone contour. Although claim 12 of the '174 patent does not teach that the surgical plan based on 3D model is a particular surgical plan for bone distraction that includes such considerations as locations on the bone where to dispose fixators, or settings of struts of fixators, for preparing surgical plan of particular procedure, bone distraction surgery, it would have

been obvious to gather or determine the required information such as fixator frame mounting location and orientation, frame size, bone dimensions, etc., and make decisions based on computational method of generating 3D model of a bone.

6. Claims 1,2, 4-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of US 6711432. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '432 patent is directed to method of generating an updated surgical plan, the method comprising: generating a three dimensional (3D) model of a bone; based on the 3D model, generating a surgical plan including: one or more locations on the bone upon which to dispose one or more markers for receiving one or more guides for guiding one or more surgical tools, and one or more settings of the one or more guides; based on the surgical plan, disposing the one or more markers on the bone; and, based on data associated with the placement of the one or more markers disposed on the bone, generating an updated surgical plan including updated settings for the one or more guides. Although the claims of '432 do not teach address a particular surgical plan for bone distraction that includes such considerations as locations on the bone where to dispose fixators, or settings of struts of fixators, for preparing surgical plan of particular procedure, bone distraction surgery, it would have been obvious to gather or determine the required information such as fixator frame mounting location and orientation, frame size, bone dimensions, etc., and make decisions based on computational method of generating 3D model of a bone.

***Prior art made of record***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

US 5408409 is directed to a surgical planning system, comprising:  
means for inputting first data specifying cross-sectional images of a region of tissue into which a device is to be implanted;  
means for inputting second data specifying a three dimensional representation of the device; and  
data processor means, responsive to inputs from an operator of the system and to the first data and the second data, for interactively superimposing a cross-sectional image of the three dimensional representation of the device to be implanted

***Conclusion.***

8. No claims are allowed


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571)272-0720 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./  
Primary Examiner, Art Unit 1631

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/636,052	KRAUSE ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	